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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,850	12/21/2000	Martin Jager	99/044NUT	4425
7590	04/14/2004		EXAMINER	
ProPat LLC 2912 CROSBY ROAD Charlotte, NC 28211			PRATT, HELEN F	
			ART UNIT	PAPER NUMBER
			1761	
DATE MAILED: 04/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No. 09/747,850	Applicant(s) JAGER ET AL.	
	Examiner Helen F. Pratt	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-24 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-20, 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 further requires "producing spherical structures from the enriched medium". However, no method has been claimed which shows how the spherical structures are produced.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-10, 20, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al.

The claims are rejected for the reasons of record and for these further reasons. Claim 1 has been amended to require that the composition is for human ingestion and is surrounded on all sides by a shell forming substance. Ueda discloses a feed additive for ruminants. However, nothing has been shown that the feed would not have been suitable for humans. Certainly, it would have been within the skill of the ordinary worker to not use particular ingredients if the product was for humans. In a composition only

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the composition needs to be shown. Ueda discloses a core made of crystalline celluloses, (col. 4, lines 49-54), and a biological substance which is in a spherical form which is coated with fat and chitosan (a polysaccharide), (col. 4, lines 59-70). The core can be coated using any conventional coating method, such as a fluidized bed coating, pan coating, and melt coating (col. 6, lines 6-10). Nothing has been shown that the composition as disclosed by Ueda et al. is not fully surrounded by the coating. Fig. 1 of Ueda discloses a core fully surrounded by the coating and the reference recognized that the amount of coating in the composition influences the properties of the coated particle, such as the ability to protect the biologically active substance. Therefore, it would have been obvious to make a composition, which has a coating, which surrounds the core as shown by Ueda et al.

Claim 20 further requires that the shell-forming substance forms a stable complex with the core or biologically active substances. Nothing is seen at this time that such does not happen because certainly liquid substances such as the disclosed cellulose would combine with the core or active substances. Therefore, it would have been obvious to make a complex with the core or biological substance.

As to limiting the shell components to particular well known polysaccharides, nothing new is seen in these polysaccharides instead of the chitosan of the reference as in claim 25. Therefore, it would have been obvious to use the claimed polysaccharides in place of chitosan absent a showing that this composition was not suitable.

Claims 1, 2, 6, 8-10, 12-20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghani (6,120,811) in view of Ueda.

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The claims are rejected for the reasons of record cited in the last office action.

Ghani discloses coated enzyme compositions used in the food industry as now required in claim 1. Nothing has been shown that the core has not been surrounded on all sides by the shell. Therefore, it would have been obvious to make a composition as shown by Ghani.

Ghani discloses a fiber, (ground corn cob or cellulosic-type material - col. 2, lines 30-35) combined with an enzyme and biological material, coated with a food grade polymer which is sprayed onto the granulated particle to envelop or hold the granule together (co. 4, lines 8-12). As the particular ingredients are only claimed broadly, it is seen that the shell forming substance does complex with the core (carrier and enzyme) as it holds the ingredients together. Therefore, it would have been obvious to make the composition as in claim 20.

Claim 25 further requires particular ingredients for the coating. The reference discloses the use of Keltone TM/Maltrin coating. Maltrin is most likely a maltodextrin absent a showing to the contrary. Therefore, it would have been obvious to coat with one of the claimed components of claim 25.

Allowable Subject Matter

Claim 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 21-24 are allowed.

ARGUMENTS

Applicant's arguments filed 3-3-04 have been fully considered but they are not persuasive. Applicants argue that the feed additive is in the form of microgranules. However, in a composition claim, it is the composition which is given weight and not the form it is in. In addition, Ueda is not limited to microgranules and states that the method of coating the core is not specifically defined (col. 6, lines 6-10).

Applicants argue that Ueda does not teach the use of microorganisms in the composition and requires a particular particle size. However, no claims are seen to the particle size. No particular ingredients are required in claims 1 and 20 except for fiber, which would show any criticality in encapsulating microorganisms. Therefore, the compositions of the references are seen to have been suitable.

Applicants argue that as in claims 3 and 20 that the shell materials form complexes with the biologically active substances, but do not state what either of the ingredients are, so that it is seen that the references read on the claims.

Applicants argue that ruminants have different digestive systems than humans. However, applicants are claiming a composition, which is a food, and no weight is given to the intended use.

It is seen that Ueda does teach structures incorporating dietary fiber, as particularly in claims 1 and 20 no particular fiber is claimed and a fiber was disclosed as above.

Applicants argue that Ueda does not teach an encapsulated structure. Nothing has been shown by the way of a showing that the shell of Ueda is not encapsulated on all sides. See fig. 1. Certainly, the process is not given weight in a composition claim.

Applicants refer to Dr. Kunz's declaration. However, the reference is not limited to microencapsulated substances and further the claims are not process claims, but composition claims, in which only the composition needs to be shown.

It is seen that Ueda does teach shell forming with biological active substances as in claim 20. Ueda discloses a biologically active substance, which can be a feed (col. 4, lines 11-15, or a grain powder, or feather powder (lines 24 and 25). All of these materials are known fibrous materials because they contain cellulose or as in feather powder, other fibers. These materials are mixed with a binder (lines 49 –54), and then coated with oils and chitosan. As no particular materials are claimed, it is seen that the fibers materials do complex with the chitosan and oil, absent a showing.

As to limiting the shell components to particular well known polysaccharides, nothing new is seen in their choice instead of the chitosan of the reference as in claim 25.

Applicants argue as to Ghani that these microgranules are designed upon combination with food ingredients. However, nothing is seen in the claims about dissolving.

As to the composition of Ghani (page 17) applicants' claims are limited to ingredients, which exclude these ingredients, and no size is even mentioned in the claims, nor is the particular method of making the granules given weight and nothing

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has been shown that the granules are not fully encapsulated. Nothing has been shown that the complexes of Ghani do not form stable complexes, which is difficult to disclose absent one knowing what the actual ingredients are.

The reference is not limited to only the use of algin, but can be gellan gums and other water-soluble food grade polymers (col. 2, lines 55-58). Certainly, the polysaccharides claimed in claim 25 are also water-soluble.

Applicants argue that there is no motivation to combine the references. However, they are each used for what they teach. No weight is given to when the microgranules dissolve, because no limitations as to such are seen in the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HP 4-12-04

H. Pratt
HELEN PRATT
PRIMARY EXAMINER